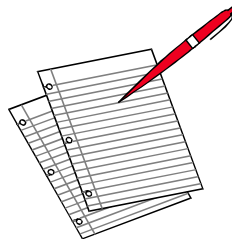


# **CDRH Background Package**



**Clinical Chemistry and Clinical Toxicology Devices Panel Meeting**

**October 29, 2001**

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## **Nature of the Problem**

Until a few years ago, only blood samples taken from the fingertip were recommended for use with glucose meters. In the past few years, however, certain glucose meters have been cleared for marketing that allow for diabetics to use blood samples collected from alternate sites, such as the forearm, upper arm, thigh, or base of the thumb. Blood glucose measurements at these sites correlate well with fingertip readings during periods when glucose levels are stable.<sup>1-2</sup>

More recent studies that have examined the relative measurements between fingertip and alternate site samples observed that blood glucose levels from alternate sites may lag behind those taken from the fingertip.<sup>3-5</sup> For example, a patient with hypoglycemic unawareness was measured with an alternate site reading of 142 mg/dl, in the mildly hyperglycemic range, while the fingertip reading was measured at 51 mg/dl, in the hypoglycemic range.<sup>3</sup>

One study reported that rubbing the collection site prior to puncture may decrease the differences between fingertip and alternate site readings.<sup>5</sup> At present, there is insufficient information to fully evaluate the effectiveness of this practice.

FDA is convening a meeting of the Clinical Chemistry and Clinical Toxicology Devices Panel on October 29, 2001 to address concerns related to blood glucose monitoring at alternate sites. The panel meeting will include presentations from the FDA, industry, and other stakeholders.

## **References**

1. Fineberg SE, Berganstal RM, Bernstein RM, et al: Use of an automated device for alternative site blood glucose monitoring. *Diabetes Care* 24:1217-1220, 2001.
2. Cunningham DD, Henning TP, Shain EB, et al: Vacuum-assisted lancing of the forearm: an effective and less painful approach to blood glucose monitoring. *Diabetes Technol Ther* Winter; 2(4):541-8, 2000.
3. Jungheim K and Koschinsky T: Risky delay of hypoglycemia detection by glucose monitoring at the arm. *Diabetes Care* 24:1303-1304, 2001.
4. Ellison J, Stegmann J, Colner S, et al: Arm and thigh capillary blood glucose as an alternative to fingertip sampling in the management of diabetes. 61<sup>st</sup> Annual Meeting and Scientific Sessions, American Diabetes Association, June 22-26, 2001, Philadelphia, Pennsylvania.
5. McGarraugh G, Schwartz S and Weinstein R: Glucose Measurements using blood extracted from the forearm and the finger. *Diabetes Care* 24:1304-1306, 2001.

# DRAFT

## CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES PANEL MEETING

**Gaithersburg Hilton, Salons A-D**  
***October 29, 2001***

Panel Chair: Martin H. Kroll, M.D.  
Executive Secretary: Veronica J. Calvin, M.A.  
Division Director: Steven I. Gutman, M.D., M.B.A.  
Deputy Division Director: Donald J. St. Pierre  
Branch Chief: Jean M. Cooper, M.S., D.V.M.

**Agenda:** The committee will provide advice and recommendations on the types of data and/or labeling needed in 510(k) submissions for glucose test systems to address problems associated with using blood samples from alternate sites, such as the forearm, upper arm, thigh, calf, or base of the thumb.

8 a.m.	<b>Call to Order</b> . . . . . Panel Chair
	<b>Opening Remarks</b> . . . . . Dr. Bernard Statland Director, Office of Device Evaluation
	<b>Conflict of Interest Statement</b> . . . . . Executive Secretary
	<b>Introductions</b>
8:15 a.m.	<b>FDA Presentation</b>
8:45 a.m.	<b>Sponsors Presentations</b>
10 a.m.	<b>Break</b>
10:15 a.m.	<b>Sponsors Presentations</b>
11 a.m.	<b>Open Public Hearing</b> <i>Public attendees, who contacted the Executive Secretary prior to the meeting, will address the panel and present information relevant to the agenda. Speakers are asked to state whether or not they have any financial involvement with manufacturers of glucose test systems.</i>
12 p.m.	<b>Lunch</b>
1:00 p.m.	<b>Open Committee Discussion</b> <i>This portion of the meeting is open to public observers. Public observers may not participate except at the specific request of the Chairperson.</i>

2:45 p.m.        **Break**

3 p.m.            **Open Public Hearing**

*Public attendees, who contacted the Executive Secretary prior to the meeting, will address the panel and present information relevant to the agenda. Speakers are asked to state whether or not they have any financial involvement with manufacturers of glucose test systems.*

3:30 p.m.        **Open Committee Discussion**

*This portion of the meeting is open to public observers. Public observers may not participate except at the specific request of the Chairperson.*

4:15 p.m.        **Final Panel Recommendations**

4:30 p.m.        **Closing Remarks**

**Adjourn** ..... Panel Chair

## **Clinical Chemistry and Clinical Toxicology Devices Panel Meeting**

October 29, 2001

### **DRAFT PANEL QUESTIONS**

- Should FDA's review of SMBG devices include dynamic as well as steady state data or are there more appropriate and less burdensome ways to address this public health issue? If additional data are necessary to characterize device performance with alternate site samples, what is an appropriate study design that will capture potential discordance during episodes of rapidly rising and falling glucose levels?
- What are appropriate analytical or statistical tools to be applied to the data (i.e., standard regression analysis, Clark Error Grid analysis, time elapsed plots)?
- Should FDA require that manufacturers include strong cautionary labeling about this problem unless data are provided which demonstrate that the discordance is not likely to happen with their particular device?
- Should FDA re-look at the current legally marketed devices and (i) rescind the clearance for alternative site testing if the applications do not address this new scientific issue, (ii) make these products prescription home-use, or (iii) require additional data and label changes?
- Are there other activities or issues that FDA should consider with regard to this important public health issue, such as a public health alert and/or educational outreach activities to stakeholders and other government and non-government entities to promote additional research in this area?

### **Questions Provided to AdvaMed**

FDA generated the following questions to help the industry prepare for the October 29, 2001 Clinical Chemistry and Clinical Toxicology Devices Panel meeting.

1. Does your company market any alternate site glucose testing system?
2. Have you tested (evaluated) for physiological/equilibration concerns as part of the pre-analytic error?
3. What was the nature of the study(ies) and what were the conclusions?
4. Are there any unique aspects of your device that would increase or minimize these differences?
5. How will you modify (or how have you modified) your labeling to address these issues?
6. Specifically what advice do you recommend to the patients who would be using these devices?
7. What additional studies need to be done?